IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

NATERA, INC., Plaintiff, v. NEOGENOMICS LABORATORIES, INC., Defendant.	)	C.A. No. 1:23-CV-629

DECLARATION OF VISHAL SIKRI IN SUPPORT OF NEOGENOMICS LABORATORIES, INC.'S MOTION FOR CLARIFICATION

FILED UNDER SEAL

I. Background

1. I serve as President of the Advanced Diagnostics Division of NeoGenomics Laboratories, Inc. ("NeoGenomics") and I submitted a prior declaration in this case dated October 18, 2023 in support of NeoGenomics's Opposition to Natera, Inc.'s Motion for Preliminary Injunction (D.I. 112). That declaration sets out my experience, as well as additional background relevant to this case and defines some of the terms that I use here.

II. Ongoing Clinical Trials

2. As I explained in my prior declaration, NeoGenomics has worked with various research organizations to conduct clinical trials and numerous cancer patients are enrolled in those clinical trials. (D.I. 112, ¶¶ 27-39). It is my understanding that clinical trials that are in progress are not impacted by the preliminary injunction, but NeoGenomics seeks clarification as to seven additional clinical trials.

3. NeoGenomics currently has three contracts for clinical testing and use of RaDaR that have been signed by all relevant parties, but for which actual testing of samples has not yet begun. These contracts are for the [redacted] All of these have protocols approved by the sponsoring research organization and have been approved by the research organization's institutional review board and ethics board for a test utilizing the RaDaR assay. If these tests are not able to utilize the RaDaR assay, they will either be cancelled because they cannot proceed without the high sensitivity of RaDaR

or will be significantly delayed while the protocols are redesigned and then reviewed again by the institutional review boards and ethics boards.

4. NeoGenomics also has four contracts for clinical testing and use of RaDaR that are well into the drafting and negotiation stage, but which have not yet actually been signed by the parties. These contracts are with [redacted]. In each case, the client has selected NeoGenomics as its preferred vendor, but the parties have not yet finalized the precise terms of the contract. One contract was literally in the queue waiting to be signed on the day the preliminary injunction was issued. Although the contract with NeoGenomics has not yet been signed, two other studies have protocols approved by the sponsoring research organization and have been approved by the research organization's institutional review board and ethics board for a test utilizing the RaDaR assay. If these tests are not able to utilize the RaDaR assay, they will either be cancelled because they cannot proceed without the high sensitivity of RaDaR or will be significantly delayed while the protocols are redesigned and then reviewed again by the institutional review boards and ethics boards. And the sponsoring research organization has done a significant amount of work to design the fourth study.

5. Enjoining NeoGenomics from completing those contracts would unduly disrupt the important clinical work of third parties, requiring them to either abandon the trial or start from scratch seeking a new partner. Some of these clinical tests could not be

conducted because of the limitations of the Signatera test (including but not limited to sensitivity and samples being unable to be tested by Natera's platform). *See also* D.I. 112 ¶¶ 29–39, 43. Even where it is possible to do so, changing to a different assay would require extensive modifications to the study protocol. These third parties may also need to fully qualify any new analytical laboratories prior to beginning the trial, a process that can add weeks or months to a study start date. The associated delays could jeopardize patients' access to the clinical trial therapies, prevent the testing or utilization of treatment options and forestall innovative interventional clinical trial designs.

III. Scientific Reporting in Publications and Conferences

6. Researchers and clinicians are understandably tremendously interested in innovations that can improve treatment and outcomes for cancer patients. Thus, there is a robust exchange of scientific information and presentation of research results, analyses of data and educational information at scientific conferences and in scientific publications.

7. Several abstracts that present clinical research, updated analysis and longitudinal monitoring of cancer patients utilizing the RaDaR assay have been accepted and are scheduled to be presented at upcoming scientific conferences, including by third-party authors, such as the American Association for Cancer Research ("AACR") Annual Meeting, which will take place April 5-10, 2024 in San Diego, CA. In addition, clinical research and analyses utilizing the RaDaR assay have been submitted to scientific journals or are pending submission to scientific journals. All of this research was completed at least a month before the preliminary injunction was issued.

8. It is in the public interest for the results of clinical research and analyses to be published and available to scientists. Given the preliminary injunction, the RaDaR assay will not be used except as allowed in the injunction, so Natera will not be harmed by these publications.

IV. Patient Harm

9. Cancer patients are an extremely vulnerable population and clinical decisions regarding treatment are often particularly time sensitive, especially at the early post-operative timepoints when RaDaR is utilized. In addition, the blood samples used for RaDaR require specialized and expedited handling because they are not stable and deteriorate quickly. Thus, it is imperative that NeoGenomics immediately process blood samples when they are received. If NeoGenomics were to return the blood samples, the elapsed time would mean that the samples had deteriorated beyond usability and could not be sent to Natera or another company to be sequenced, so they would need to be discarded and the clinician would need to start again by drawing another blood sample. This delay would in turn delay time-sensitive treatment decisions.

10. As of December 28, 2023, the test requisition for RaDaR is no longer available, meaning that it is no longer possible to request RaDaR tests for new patients. However, given the stability issues of blood samples, NeoGenomics will continue to process samples that were requisitioned prior to the issuance of the preliminary injunction, but received after it was issued. The volume of such patients is expected to be less than 100 patients.

V. Harm to NeoGenomics From Preliminary Injunction

11. NeoGenomics has already sustained significant damages as a result of the announcement of the preliminary injunction and will continue to do so.

12. NeoGenomics completed its acquisition of Inivata on June 18, 2021 for a purchase price of over [redacted] This amount does not include the additional investment NeoGenomics has continued to make into RaDaR, more than [redacted] over the last 2 years, which does not include the costs of operations or clinical data generation. This investment is lost as a result of the preliminary injunction.

13. On December 27, 2023, prior to the announcement of the preliminary injunction order, NeoGenomics's stock closed at a price of $20.50 per share. On December 28, 2023, after the announcement of the preliminary injunction order, NeoGenomics's stock opened at a price of $18.05 per share and closed at $16.79 per share at the end of the trading day. Based on 127,465,820 shares outstanding as on 11/2/23 (as reported in the latest NeoGenomics10Q), NeoGenomics's market capitalization dropped from $2.613 billion on December 27, 2023 to $2.14 billion at the end of the day on December 28, 2023, a loss of approximately $475 million.

14. In addition, NeoGenomics has incurred additional research and development costs, as well as costs in generating clinical data and other internal studies.

15. As a direct result of the preliminary injunction, NeoGenomics will incur additional costs because RaDaR assay kits and components have a limited shelf life. Some number of kits and reagents, as well as the raw materials to create new kits, will expire

during the pendency of the preliminary injunction and cannot be sold. In addition, NeoGenomics has incurred costs for marketing materials and promotional opportunities that have to be abandoned as a result of the preliminary injunction, plus fees to agencies and professionals in conjunction with these marketing and promotional materials, none of which are recoverable. Other costs directly resulting from the grant of the preliminary injunction include depreciation of equipment and costs to redeploy the sales force and other personnel, storage costs of unused/unusable kits and raw materials and other supply chain costs. NeoGenomics is still in the process of determining these costs, but can provide documentation upon request.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 29th day of December, 2023.

Vishal Sikri